INTRODUCTION

There sometimes comes a time in the existence of any structure, whether it is physical or conceptual in nature, when the structure is beyond fixing, and the only reasonable alternative is to replace it altogether. Such a time is long over due for the classification system for ankle joint replacement devices. However useful defining generic types by degrees of constraint may have seemed at the time ankle devices were last classified, Federal Register, Vol. 69 No. 189, no reasonably safe and effective ankle replacement device has emerged from its use. The current classification methodology, based solely on constraint characteristics, is fundamentally flawed. There is more to defining a safe joint than constraint. A classification description should include all those important elements that define a safe device.

The current classification protocol prevents the general use of lower risk devices that provide more natural stability and lower contact stress than devices now on the market. Thus the current protocol acts against the public good. It accepts and fosters device types that are well known to be not safe.

The most fundamental reason for a new classification type is that the determination of the class of a device should be based on the risks and benefits of the device, a consideration of the alternative treatments available, and the necessity to apply the least burdensome means rule in evaluating the data and options in accordance with the Modernization Act of 1997.

"The choice to use a ... device involves balancing the benefits to be gained with the potential risks of using a product.... Although medical products are required to be safe, safety does not mean zero risk, since all medical products are associated with risks. A ***safe medical product*** is one that has reasonable risks, given the magnitude of the benefit expected and the alternatives available." [i]

Applying this criteria, when reviewing the material in this petition, one may conclude that the B-P Total Ankle Replacement:

- Is stable given that the accepted test for ankle stability is applied, " The stability required of successful ankle replacement is a combination of extrinsic stability, provided by bone and ligamentous support, and intrinsic stability, a function of implant geometry." [ii] The FDA has classified the B-P ankle device as class III due to its stability characteristics. They consider this device to be non-constrained. Yet the device has more normal and less risky stability characteristics than devices that would be classified as class II under the current classification protocol. The B-P device produces an ankle that has essentially normal stability properties after implantation.
- Greatly reduces the risks of loosening and high wear associated with overconstraint and incongruity. Certainly the B-P device should not be prevented from being sold because it fails to over constrain the ankle or it fails to provide unnecessary constraints and thereby fails to produce well-known, unnecessary, risk of loosening

i Managing The Risks From Medical Product Use Creating A Risk Management Framework, Report to the FDA Commissioner from the Task Force on Risk Management, U.S. Department of Health and Human Services Food and Drug Administration, May 1999

ii Conti, F et al, 'Update on Total Ankle Replacement', *Seminars in Arthroplasty*, Vol. 10, No. 2, April 1999, 62-71

associated with such constraints. Additionally when considering the high loads that apply to the ankle, a device like the B-P device that reduces high contact stresses has the benefit of much lower wear.

- Is an alternative that has fewer risks and greater benefits with regard to stability, mobility, function, and elimination of pain than the other alternatives. Most of the ankle joint replacement devices have failed miserably, and ankle fusion has come under increasing criticism over the last decade, making the need for a viable, safe, and effective ankle device such as the B-P device imperative.

We thus propose a new methodology and description for classification and recommend the abandonment of the current system. To make the new methodology work properly it is important that the requirements of the Modernization Act of 1997 be effectively used in the application of any new regulatory protocol. Thus, it is probably more important to consider risks and benefits of devices to be classified with, perhaps, greater weight given, than strict adherence to a particular interpretation of the classification definition.